This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit within 60 days from the effective date of this rule. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This rule may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection; Administrative practice and procedure; Air pollution control; Intergovernmental relations; Reporting and recordkeeping requirements.

Dated: April 10, 2009.

Beverly H. Banister,

Acting, Regional Administrator, Region 4.

■ 40 CFR part 62, subpart RR, is amended as follows:

PART 62—[AMENDED]

■ 1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart RR—Tennessee

■ 2. Section 62.10626 is amended by adding paragraphs (b)(6) and (c)(3) to read as follows:

§ 62.10626 Identification of plan.

* * * * *

(b) * * *

(6) City of Memphis Implementation Plan: Federal Emission Guidelines Hospital/Medical/Infectious Waste Incinerators (HMIWI), submitted on February 16, 2006, by the Memphis and Shelby County Health Department.

(c) * * *

(3) Existing Hospital/Medical/Infectious Waste Incinerators

■ 3. Part 62 is amended by adding a new undesignated center heading to subpart RR and a new § 62.10632 to read as follows:

Air Emissions From Existing Hospital/Medical/Infectious Waste Incinerators (HMIWI)—Section 111(d)/129 Plan

§ 62.10632 Identification of sources.

The Plan applies to all existing HMWI facilities at St. Jude Children's Hospital in the City of Memphis, for which construction was commenced on or before June 20, 1996.

[FR Doc. E9–13595 Filed 6–9–09; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0395; FRL–8412–1]

Residues of Silver in Foods from Food Contact Surface Sanitizing Solutions; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the exemption from the requirement of a tolerance for residues of silver (excludes silver salts) in or on all foods when applied or used in public eating places, dairy processing equipment, and food-processing equipment. ETO H2O, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act requesting to establish concentration limits for silver in end-use solutions eligible for tolerance exemption. The regulation being established will exempt all foods from the requirement of a tolerance for residues of silver resulting from contact with surfaces treated with solutions in which the end-use concentration of silver is not to exceed 50 parts per million (ppm).

DATES: This regulation is effective June 10, 2009. Objections and requests for hearings must be received on or before August 10, 2009 and must be filed in accordance with the itructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0395. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Marshall Swindell, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–6341; e-mail address: *swindell.marshal@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a dairy cattle milk producer, food manufacturer, or beverage manufacturer. Potentially affected entities may include, but are not limited to:

- Food Manufacturing (NAICS code 311).
- Beverage Manufacturing (NAICS code 3121).
- Dairy Cattle Milk Production (NAICS code 11212).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 180.940 (a) Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions). If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://*

www.regulations.gov, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0395 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 10, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0395, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001.

- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The docket telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of July 11, 2007 (72 FR 37779) (FRL–8136–1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of an pesticide tolerance petition (PP 7F7178) by ETO H20, Inc, 1725 Gillespie Way, El Cajon, CA 92020. The petition requested that 40 CFR 180.940(a) be amended by establishing concentration limits for Silver in end-use solutions eligible for the tolerance exemption in all foods from treatment of food contact surfaces in public eating establishments, dairy processing equipment, and food processing equipment and utensils not to exceed silver at 50 ppm. The notice referenced a summary of the petition prepared by ETO H20, Inc., 90 Boroline Rd Allendale, NJ 07401, the registrant, which is available to the public in the docket at *www.regulations.gov*, Docket ID Number EPA–HQ–OPP–2007–0395. There were no comments received in response to the notice of filing.

In drafting the regulatory language for this exemption, EPA has adopted more restrictive language than suggested in the petition to ensure that the scope of the exemption does not exceed the form of silver evaluated in the risk assessment supporting this action. As revised, the tolerance expression would now read:

> Silver ions resulting from the use of electrolytically-generated silver ions stabilized in citric acid as silver dihydrogen citrate (does not include metallic silver).

This revised tolerance expression excludes any other silver-containing compounds whether they are other silver salts, complexes with inorganic polymers such as zeolites, or metallic silver in any form or dimension including nanoscale.

EPA understands that this petition was not intended to extend to silver salts accordingly EPA has modified the regulatory language to make this clear.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

A. Toxic Effects

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by silver are discussed in this unit.

Silver ions and preparations containing silver in an ionic state have been used for over a century for medicinal and bactericidal purposes. Because of its bactericidal properties, silver has been used as a topical treatment for burns, as a treatment for venereal diseases, as an ingredient in cosmetic formulations and in the sanitation of swimming pools and hot tubs/spas. Silver has also been used in dentistry (as amalgams and as an ingredient in mouth washes), in acupuncture, jewelry making, and photography. Silver can be found in electroplating as well as in paints and in water purification systems.

The toxicity of silver is well understood based on epidemiological data from humans, toxicology data in animals, and documented information on the metabolism of silver in mammalian species. Unlike for other pesticides, EPA does not have a conventional check-list of guideline laboratory animal studies to assess human risk from exposure to silver. Based on the extensive past uses of

silver and EPA's knowledge and experience about those uses of the compound, however, it is apparent that humans and laboratory animals do not handle elevated doses of silver in the same manner. For this reason, additional conventional laboratory animal toxicity studies would not provide a better understanding of the effects of silver in humans. Further, the Agency has determined that silver and several of its salts (chloride, sulfate nitrate and acetate) can be reviewed together because these silver salts react similarly in aqueous media and the major active ion is the silver ion.

A human biomonitoring study conducted in 1935, as reported in the *Journal of the American Medical Association* by L.E. Gaul and H.E. Staud, has served as the basis for establishing regulatory limits for silver in drinking water and in the diet. The results from this study were further supported by the results from an inhalation study conducted by Pillsbury and Hill in 1939, which established inhalation limits for silver in humans. In both studies, the effect of concern was argyria, a bluish discoloration of the skin. Argyria, while a permanent condition, is a cosmetic condition. The function of the skin as an organ is not compromised and the resulting discoloration is not associated with systemic toxicity. In the 1935 study by Gaul and Staud, silver was administered for medicinal purposes to 70 patients for periods from 2 to 9 years. Of the 70 patients receiving medicinal silver, 1/70 developed argyria after receiving an intravenous dose of 1 gram. This intravenous dose was converted to an oral dose of 0.014 milligram/kilogram/day (mg/kg/day) and was considered a lowest observed effect level. Other patients did not develop argyria until doses five times higher were administered. This study and an inhalation biomonitoring study by Pillsbury, *et al*, clearly determined the endpoint of concern for humans. Interestingly, the skin form of argyria has not been reported in laboratory animals when doses that are approximately 4 orders of magnitude higher (100 mg/kg) are administered.

Further support for not requiring additional laboratory animal studies for silver is provided from the results of the developmental toxicity study in rats, conducted by the National Toxicology Program (NTP). In a developmental study conducted in 2002, silver acetate was administered by gavage on days 6 – 19 of gestation. No developmental effects were reported at doses up to 100 mg/kg; maternal animals were observed to have piloerection and rooting behavior at 30 mg/kg. The observed effects in maternal animals would not be expected to occur in humans and are frequently observed in animal studies. These observations, when made in the absence of other clinical findings are not considered adverse when establishing a ''no adverse effect level.'' More importantly, the results from this study did not demonstrate an increased susceptibility of offspring, nor did it demonstrate systemic toxicity. This study corroborates the use of the information provided by the human biomonitoring study in determining dietary limits for silver and further supports our decision to not rely on animal data when assessing the health effects of silver in humans.

In addition to the information gleaned from the biomonitoring studies and the developmental toxicity study, the reviews of the literature by other EPA offices and national and inter-national organizations provide supplemental support that argyria is the primary effect in humans (e.g. EPA's Integrated Risk Management System, Agency for Toxic Substances and Disease Registry, the World Health Organization). Also the acute oral toxicity studies that have been provided to support the registration of silver as an antimicrobial agent establish LD_{50s} between 2,000 and 5,000 mg/kg. These values are above the limit dose for acute toxicity. For other silver salts, such as silver cyanide, the LD_{50} values may be significantly lower based on the molecules to which the silver ions are attached. For the antimicrobial silver covered by this exemption, the LD_{50} ranges are very high because the silver ions have very low acute toxicity.

Finally, the pharmacokinetics of silver is understood and may explain the low systemic toxicity potential of the compound. Pharmacokinetics describes what the body does to a chemical when it is introduced into the body including how it is metabolized, distributed, and eliminated. When silver is introduced into the body by the oral or dietary route, it is absorbed by the digestive system and then enters the liver before it reaches the rest of the body (referred to as first-pass metabolism). This first pass through the liver greatly reduces the bioavailability of silver in that about 90% of the orally administered dose is eliminated in the feces. The remaining 10% that is not eliminated in the feces, reacts with proteins by binding to a specific chemical group contained in the structure of the protein. By forming silver-protein complexes through this binding action, the remaining silver is removed from circulation. This remaining fraction accounts for the background levels of silver that are found within the body. At excessive doses, the pathways of elimination become saturated and deposition of these complexes in the tissues is increased. The formation of these complexes and deposition in the skin, mucous membranes, and conjunctiva is the primary mechanism which results in the development of argyria. Based on information from biomonitoring studies, the lowest observed effect level for the formation of argyria was 1 gram (total dose), which was converted to an oral dose of 0.014 mg/kg/day.

B. Regulatory Levels

Safe exposure levels for silver have been established by several regulatory Agencies including the Food and Drug Administration, Occupational Safety and Health Administration and other offices within EPA based on the common endpoint argyria and using the same human studies. Argyria is a blue-gray discoloration of the skin and is not considered as being of toxicological concern. Argyria is cosmetically disfiguring and permanent in nature; however, the occurrence of this condition does not adversely affect organ function or threaten human health. EPA believes that by regulating for argyria, it is protecting the public from this permanent cosmetic effect as well as any potential toxic manifestations of silver that may occur at much higher doses. There is no animal condition that would mimic the dermatologic form of argyria found in humans following exposure to silver by various routes. This may be due in part to the protection imparted by the presence of the fur or by the fact that laboratory animal species are not routinely exposed to direct sunlight. Argyrosis, a form of argyria which involves silver deposition in organs, has been documented. In laboratory species, the effects of silver toxicity have been reported to involve pathology to the liver (necrosis) and kidney (thickening of the basement membranes of the glomeruli), and, at elevated levels, death.

The effect on which silver is regulated (argyria) occurs only after chronic exposure. Both the Secondary Maximum Contamination Level (SMCL) reported by the EPA's Office of Water and the oral reference dose (RfD) reported under the EPA's Integrated Risk Information System (IRIS) were determined based on the previously-mentioned human biomonitoring by Gaul and Staud. For the SMCL, additional mathematical derivations were applied to the oral equivalent dose

to the study Lowest Observed Adverse Effect Level (LOAEL) of 0.014 mg/kg/day to obtain a 0.1 milligram/Liter (mg/L) dose level. The factors applied for changing volume to mass account for the slight difference in the values reported for the SMCL (0.003 mg/kg/day) and for the RfD (0.005 mg/kg/day).

In deriving the chronic dietary regulatory level (RfD) and the SMCL, a safety factor of 3X was applied based on the following rationale as reported by the Office of Water and IRIS. First, the critical effect was cosmetic and not of toxicological significance. Second, the derivation of the LOAEL included the most sensitive individual since other patients did not present with argyria unless dose levels five times higher were administered. Finally, in the human biomonitoring study, silver was administered to these individuals over a period of time that is in excess of chronic exposure and that approaches a level that would be considered a life time exposure duration. Therefore, the dose that was administered was determined as being one that would mimic lifetime exposure.

For the oral exposure route, the Agency is relying on the drinking water Secondary Maximum Contaminant Level (SMCL) of 0.1 mg/L (0.003 mg/kg/day) based on skin discoloration and graying of the whites of eyes (argyria). The Agency applied an additional 3X uncertainty factor to further address the lack of a NOAEL in the study on which this assessment and all regulatory advisories are set. This additional 3X factor was not imposed due to the lack or need for additional standard animal toxicity testing. Thus, a composite database factor of 10X is being applied to account for a lack of NOAEL in the Gaul and Staud (1935) study. This composite factor of 10 should be sufficient for providing protection from the non-toxic effects which may result from chronic oral exposure to silver.

Chronic Dietary Reference Dose (RFD) = 0.003 mg/kg/day ÷ 3 = 0.001 mg/kg/day

Alternatively, a roughly equivalent chronic RfD can be derived by dividing the oral equivalent dose from the Gaul and Staud study (0.014 mg/kg/day) by a factor of 10X.

Following dermal exposure, silver ions tend to bind to the skin and do not penetrate the skin to cause systemic effects. Rather, skin discoloration is the only effect induced by silver exposure through the dermal route. Although this discoloration appears to be the same effect that results from oral and inhalation exposure, the mechanism by which discoloration occurs following dermal exposure is not the same as the mechanism leading to argyria following other routes of exposure. Systemic uptake and distribution of silver following dermal exposure does not occur, and the discoloration is the result of a localized reaction. Again, the effect is not adverse and there is no reason to believe that there would be an increase in susceptibility based on age to the nontoxic discoloration. Susceptibility to this cosmetic event is a function of dose and not age.

IV. Aggregate Exposures

To establish a tolerance, it must be shown ''that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information.'' Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation).

Silver is commonly used for a variety of non-pesticidal industrial uses, which include but are not limited to photography, cosmetics, sunscreens, manufacture of inks and dyes, mirror production, and in jewelry. These sources result in primary exposures being via the dermal route. As previously mentioned, the consequence of silver exposures via the dermal route is dermal argyria, which does not contribute to the systemic argyria induced by oral and inhalation routes of exposures. Silver has also been used in dentistry (as amalgams) and as an ingredient in mouth washes. However, there is no documented evidence of argyria developing from dental or mouth wash uses of silver despite its widespread and frequent use in dentistry for over a century; consequently, EPA concludes that the level of exposure from the dental and mouthwash uses is negligible. Therefore, EPA did not aggregate the exposures resulting from these various uses with pesticidal exposure sources.

A. Dietary Exposure

Under the current proposal (PP 7F7178), silver will be used as a sanitizer for food contact surfaces, resulting in dietary, drinking water, and residential exposures. The use sites include but are not limited to: Food service facilities, cafeterias, households, kitchens, food preparation areas, food processing equipment and treated surfaces, such as countertops, equipment, and appliances. The sanitizing solution is applied to these various surfaces by spraying (trigger, spraying, coarse pump), wiping with a cloth or sponge, mopping, or by full immersion. As a result of these uses, residues are expected to transfer to the food that comes into contact with these treated surfaces and subsequently to be ingested by humans.

1. *Food*. The Agency assessed chronic dietary exposure from the use of silver as a food contact sanitizer. The dietary assessment was only completed for chronic routes because the regulatory effect that has been identified is based on argyria, one that occurs only after chronic exposure. For dietary exposures from this product being used on countertops, the Incidental Dietary Residential Exposure Assessment Model, IDREAM™ incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-1996, and 1998 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. The maximum rate for silver is 50 ppm active ingredient.

The use on utensils, dishes and glass was assessed. Based on conservative calculations, risk concerns were identified. At this time, a label restriction will be required that prohibits the use on utensils, dishes and glassware until a residue transfer study has been conducted and accepted by the Agency.

Agricultural Premises-Dairy Facilities. Dietary exposures from these general premise uses are expected to be much lower than the dietary exposure resulting from the surface disinfectant and sanitizing uses considered for this tolerance exemption: therefore, the agricultural uses were not assessed separately. However, the sanitization of food processing equipment permits product contact with the interior of equipment. The milk-truck model (described in the FDA document, ''Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions'', pages 9-10)(FDA 2003) for these types of uses was executed in order to estimate residues that could transfer from treated surfaces to food. From this guidance, it was conservatively assumed that a child will consume 320 grams of milk per day (90th percentile value) and an adult will consume 125 grams milk per day (mean value). Because EPA has utilized this maximized value for children along with a child's body weight in this assessment, EPA has confidence that the calculations are conservative and representative of any potential risks to any population.

The Agency assumes that the sanitized tank truck which transports the milk is a conservative estimate of residue that is available in food processing facilities.

Milk undergoes no additional dilution prior to reaching the consumer and it is also assumed that 100% of the residues available post sanitation is transferred to the food.

Additionally, the dietary contribution as a result of food processing equipment sanitization is so extremely small that it is considered negligible and not included in the combined or aggregate assessments.

2. *Drinking water exposure*. There are no outdoor or potable human drinking water system uses for the use of silver proposed in pesticide petition (PP) 7F7178. In addition, the uses identified as indoor hard surface applications will result in minimal, if any, runoff of silver into the surface water. The use of silver as a food contact surface sanitizer will result in minimal, if any, runoff of silver into the surface water. This use will result in an insignificant contribution to drinking water exposures. In addition to sanitization, silver is registered as an active ingredient in water filters. The bacteriostatic water filters are impregnated with silver and may result in residues in the drinking water supply. However, the levels of available residues resulting from impregnated water filters are much less when in comparison to the amount of residues that will be available for intake when silver-containing liquid concentrates are used. As a result, any drinking water exposures from the new use of silver are assumed to be negligible. Additionally, any drinking water risks from impregnated filters are assumed to be represented by the dietary risks resulting from hard surface sanitization. The Agency believes that an assessment of any potential risks resulting from silver in drinking water is not warranted at this time.

Therefore, based on the uses of silver outlined in the pesticide petition, the Agency believes that risks resulting from silver in drinking water will be negligible and that an assessment is not warranted at this time.

Table 1 provides a comprehensive summary of all of the use patterns potentially resulting in dietary exposure that were considered for this tolerance exemption.

TABLE 1.—POTENTIAL USE SCENARIOS

Use Site Category	Example Use Sites	Scenarios
Use Site Category I: Agricultural Premises and Equipment	Dairy farms, hog farms, equine farms	Application to hard surface (feeding dishes, bottling equipment, floors, etc) through coarse spraying (low pressure spray), trigger pump spray, wipe/sponge, mop, and immersion
Use Site Categories II, III, and V: Food Handling, Commercial/Institutional/Industrial, Medical	Food processing plants; Hospitals; Public places (e.g., restaurants, hotel/motel rooms); Medical/Dental offices; Nursing home; Schools, Cruise ships, Dining Halls.	Application to hard surfaces through coarse spraying (low pressure spray), trigger pump spray, wipe/sponge, mop, and immersion. Some examples of surfaces include: sinks, cutting boards, counter tops, kitchen appliances, breast pumps and parts, baby bottles, ice chests, and various others that are summarized on the proposed label.
Use Site Category IV: Residential and Public Access Premises	Homes, kitchens	Application to hard surfaces through coarse spraying (low pressure spray), trigger pump spray, wipe/sponge, mop, and immersion. Examples of the hard surfaces include those identified for Use Site Categories II, III, and V.

B. Other Non-Occupational Exposure

The residential exposure assessment considers all potential non-occupational pesticide exposure, other than exposure due to residues in food or in drinking water. Exposures may occur during and after application on hard surfaces (e.g., floors). Each route of exposure (incidental oral, dermal, inhalation) is considered where appropriate. The risks to handlers are quantitatively assessed based on the nature of the chemical. As previously stated, there are no adverse toxicological consequences (systemic or irritation) resulting from contact with silver other than skin discoloration. Residential exposures are short-term (< 30 days) and intermediate-term (1 to 6 months) in nature. As supported in the toxicological discussion, however, silver ion produces only cosmetic effects and only as a result of chronic exposures. In addition, incidental ingestion (hand to mouth behavior of a child on a treated floor) as well as dermal exposures resulting from a child contacting a freshly cleaned floor are considered short-term in duration.

Based on the fact that silver will exist in the ionic form, which does not volatilize, any post-application inhalation exposures to vapors are expected to be negligible. Essentially, there are no toxicological consequences (systematic or irritation) resulting from contact with silver other than discoloration. Table 2 outlines the use patterns and routes of exposure that were considered for purposes of a non dietary residential assessment. The Agency will request that label claim be placed on the label to advise users that prolonged contact with the product may cause skin discoloration.

Other non-pesticidal industrial uses of silver include, but are not limited to, photography, cosmetics, sunscreens, manufacture of inks and dyes, mirror production, and in jewelry. All these uses may result in exposures via the dermal route, which over a chronic duration, may cause skin discoloration. However, dermal exposures resulting from these uses are not appropriate to include in this aggregate exposure assessment. It has been previously concluded that systemic uptake and distribution of silver does not occur via the dermal route. The specific uses of silver that were considered for this aggregate assessment include the cleansing of hard surfaces in various food handling, institutional, medical and residential premises. Exposures

resulting from freshly cleaned surfaces are considered not to be of concern to the Agency.

TABLE 2.—REPRESENTATIVE USES ASSOCIATED WITH RESIDENTIAL EXPOSURE

Representative Use	Exposure Scenario	Application Method	Application Rate
Indoor Hard Surfaces	ST Handler: Dermal and Inhalation;	Liquid Pour	4.17 E-04 lb ai/gal (0.005% ai x 8.34 lb/gal)
	ST and IT Post-app[1]: child incidental ingestion and dermal	Mopping Wiping Trigger Pump Spray Low Pressure Spray (coarse spray) Immersion[2]	50 ppm silver ion

ST = Short-term exposure, IT = Intermediate-term exposure

[1] IT post-application exposures to children were assessed because this product could be used in a commercial day care facility.

[2] The handler exposures associated with liquid pouring of this product are representative of those associated with immersion (standing solution).

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding between silver and any other substances and silver does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption action, therefore, EPA has not assumed that silver has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

VI. Safety Factor for Infants and Children-

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is extensive data and analysis on silver's toxicity in the historical data/literature and the regulatory advisories established by other Federal Agencies, which do not indicate an increased susceptibility of children to the toxic effects of silver. A NTP developmental toxicity study concluded that the NOAEL recorded for developmental toxicity in rats receiving gavage doses of silver acetate, was greater than 100 mg/kg when the test material was administered on gestation days 6 through 19. No increase in susceptibility was apparent in this study. Furthermore, silver nitrate has been used for decades to treat neonatal conjunctivitis. Finally, there is no reason to believe that the effects that are observed following the administration of silver would warrant additional safety factors for children. The skin is the target organ and the deposition of silver should not be age dependent. Moreover, because EPA believes that the Gaul and Staud study adequately characterizes variability in human sensitivity, EPA is not applying an intra-species uncertainty factor in deriving the chronic RfD for silver.

3. *Conclusion*. Although EPA is not applying an inter-species uncertainty factor (because of reliance on human data) or an intra-species uncertainty factor (because human sensitivity has been adequately characterized), EPA is retaining the 10X FQPA safety factor in assessing oral risk to address the fact that the dose used to determine the chronic RfD showed effects from silver (argyria). In making this determination, EPA took into account that argyria is not a toxic effect, there is no evidence of increased sensitivity in the young, and the exposure assessment for silver is very conservative.

For dermal exposure, silver ions tend to bind to the skin and do not penetrate the skin to cause systemic effects. Thus, systemic uptake and distribution of silver does not occur following dermal exposure. Skin discoloration is the only effect due to a localized reaction. Based on the above findings, a FQPA safety factor of 1X should be applied to the chronic dietary RfD for assessing dermal exposure. An additional safety factor is not required for the protection of infants and children because there would not be an increase in susceptibility to this cosmetic nontoxic effect. This cosmetic event is a function of the dermal contact dose not age. Furthermore, the approach taken to assess risk from dermal exposure is very conservative in that the Agency has based its dermal risk assessment on the systemic oral dose that was used to establish the oral/dietary risks.

VII. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

For a tolerance to be found to be safe, it must be shown ''that there is reasonable certainty that no harm will

result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information.'' Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation).

1. *Dietary risk*. A summary of antimicrobial indirect food use acute/chronic risk estimates from exposure to treated countertops are shown below in Table 3. As explained above, EPA believes that exposures resulting from silver in drinking water will be negligible. For adults, chronic dietary exposure risk estimates are approximately 20% of the chronic PAD. For children, the most highly exposed population subgroup, the chronic dietary risk estimates are 62% of the chronic PAD. Therefore, chronic dietary exposure estimates are below the Agency's level of concern for all population subgroups.

TABLE 3.—CALCULATED EXPOSURE AND RISK RESULTING FROM SILVER SANITIZATION OF COUNTERTOPS

Exposure Group	Chronic	
	DDD(mg/kg/d) [a]	%cPAD [b]
Adult males (13+)	0.00022	22
Adult females (13-69)	0.00021	21
Children (1-2)	0.00062	62

[a] DDD (mg/kg/day) was provided from the IDREAM model.

[b] % PAD = exposure (total dietary exposure)/ PAD) x 100. The cPAD is equivalent to the chronic oral RfD value of 0.001mg/kg/day.

2. *Aggregate non-cancer risk*. Aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because any oral residential exposures will be short-term in nature, the chronic risk is equal to the estimate for dietary risk.

3. *Aggregate cancer risk for U.S. population*. Available animal and human experience through occupational and medicinal exposure scenarios have not indicated a carcinogenic potential for silver. Therefore, silver is not expected to be carcinogenic to humans particularly in light of its low systemic toxicity potential and our understanding of its metabolism.

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to silver residues.

VIII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method for food is not needed. Food contact sanitizers are typically regulated by state health departments to ensure that the food industry is using these products in compliance with the regulations in 40 CFR 180.940. The end use solution that is applied to the food contact surface is analyzed rather than food items that may come into contact with the treated surface. An analytical method is available to analyze the use dilution that is applied to food contact surfaces. The following methods of analysis are used to analyze the use dilution of silver being applied to food contact surfaces: Gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR).

B. International Residue Limits

There is not a Codex Maximum Residue Level established for silver.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Food contact sanitizers, Silver, Food additives, Pesticides and pests,

Reporting and recordkeeping requirements.

Dated: May 26, 2009.

Joan Harrigan-Farrelly,

Director, Antimicrobials Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.940 is amended by adding alphabetically the following entry to the table in paragraph (a):

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
	* * * * * * *	
Silver ions resulting from the use of electrolytically-generated silver ions stabilized in citric acid as silver dihydrogen citrate (does not include metallic silver)	14701–21–4	When ready for use, the end-use concentration of silver ions is not to exceed 50 ppm of active silver.
	* * * * * * *	

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[FR Doc. E9–13476 Filed 6–9–09; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 09–1209; MB Docket No. 08–126; RM–11458]

Television Broadcasting Services; Canton, OH

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking filed by Trinity Christian Center of Santa Ana, Inc., d/b/a Trinity Broadcasting Network (''Trinity''), the licensee of station WDLI–DT, to substitute DTV channel 49 for its assigned post-transition DTV channel 39 at Canton, Ohio.

DATES: This rule is effective June 10, 2009.

FOR FURTHER INFORMATION CONTACT: David J. Brown, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 08–126, adopted May 28, 2009, and released May 29, 2009. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via the Internet *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Ohio, is amended by adding DTV channel 49 and removing DTV channel 39 at Canton.

Federal Communications Commission.

Clay C. Pendarvis

Associate Chief, Video Division, Media Bureau.

[FR Doc. E9–13650 Filed 6–9–09; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 09–1225; MB Docket No. 08–129; RM–11461]

Television Broadcasting Services; Spokane, WA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking filed KHQ, Incorporated (''KHQ''), the licensee of station KHQ–DT, DTV channel 7, Spokane, Washington, and a related petition for rulemaking filed by Spokane School District #81 (''Spokane School District''), the licensee of noncommercial educational station KSPS–DT, DTV channel *8, Spokane, Washington. KHQ requests the substitution of DTV channel 15 for its assigned post-transition DTV channel 7 at Spokane, and the Spokane School District requests the substitution of DTV channel *7, its current analog channel, for its assigned post-transition DTV channel *8 at Spokane.

DATES: This rule is effective June 10, 2009.